

PVC Drug Safety Communication: Ondansetron (Zofran) 32 mg, Single Intravenous (IV) Dose Safety Communication - Product Removal due to Potential For Serious Cardiac Risks
5 Dec 2012

Pharmacy, Patient Safety, Oncology and Surgery communities: Please share with pharmacists and providers at your MTFs and regions.

The FDA announced the 32 mg, single intravenous (IV) dose of the anti-nausea drug Zofran (ondansetron hydrochloride) will no longer be marketed in the US because of the potential for serious cardiac risks.

BACKGROUND: The 32 mg, single IV dose of Zofran had been used to prevent chemotherapy-induced nausea and vomiting. A previous Drug Safety Communication (DSC), issued on June 29, 2012, communicated that the 32 mg, single IV dose should be avoided due to the risk of a specific type of irregular heart rhythm called QT interval prolongation, which can lead to Torsades de Pointes, an abnormal, potentially fatal heart rhythm. These drugs are sold pre-mixed in solutions of either dextrose or sodium chloride in plastic containers.

RECOMMENDATIONS: FDA continues to recommend the intravenous regimen of 0.15 mg/kg administered every 4 hours for three doses to prevent chemotherapy-induced nausea and vomiting. Oral dosing of ondansetron remains effective for the prevention of chemotherapy-induced nausea and vomiting. At this time, there is not enough information available for FDA to recommend an alternative single IV dose regimen.

Due to these safety concerns and in abundance of caution, these products should be removed from inventory and returned for credit when possible.

All sites and personnel involved in the compounding or administration of ondansetron should be aware that the 32 mg single infusion is not recommended and should not be compounded, distributed or administered in that strength.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:
www.fda.gov/MedWatch/report.htm

The complete MedWatch Safety Alert is attached and also available:
www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm330772.htm

QUESTIONS OR ADDITIONAL INFORMATION: Send requests for additional information regarding this alert or the analysis conducted by the Pharmacovigilance Center (PVC) to: otsg.pvc@amedd.army.mil